

MECLIZINE HCL 25 MG- meclizine hydrochloride tablet, chewable
Bryant Ranch Prepack

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Meclizine HCl 25 mg Chewable Tablets

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each chewable tablet)

Meclizine HCl, USP 25 mg

Purpose

Antiemetic

Uses

prevents and treats nausea, vomiting or dizziness due to motion sickness

Warnings

Do not use in children under 12 years of age unless directed by a doctor.

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product

- may cause drowsiness
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children.

In case of overdose, get medical help or contact the poison control center immediately.

Directions

- dosage should be taken one hour before travel starts.
- **adults and children 12 years of age and older:** Chew 1-2 tablets once daily or as directed by a doctor
- **children under 12 years:** do not give this product to children under 12 years of age unless directed by a doctor

Other information

- phenylketonurics: contains phenylalanine 0.28 mg per tablet
- store at room temperature in a dry place

Inactive ingredients Aspartame, croscarmellose sodium, dextrose, FD&C red #40 lake, magnesium stearate, maltodextrin, microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium

<div>MECLIZINE HCL 25 MG</div> <div>meclizine hydrochloride tablet, chewable</div>			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71335-0 143(NDC:51645-994)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
SUCROSE (UNII: C15IH8M554)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Product Characteristics			
Color	pink (Uncoated)	Score	2 pieces
Shape	ROUND (Biconvex)	Size	8mm
Flavor	RASPBERRY	Imprint Code	21G
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-0143-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2016	
2	NDC:71335-0143-8	14 in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2016	
3	NDC:71335-0143-5	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2016	
4	NDC:71335-0143-0	120 in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2016	
5	NDC:71335-0143-6	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2016	
6	NDC:71335-0143-3	25 in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2016	
7	NDC:71335-0143-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2016	
8	NDC:71335-0143-9	10 in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2016	
9	NDC:71335-0143-4	40 in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2016	
10	NDC:71335-0143-7	8 in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2016	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	10/15/2015	

Labeler - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-0143) , RELABEL(71335-0143)

Revised: 1/2020

Bryant Ranch Prepack